DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

July 31, 2002

Dr. Steven Binion
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073

Re: BK000047
Product: Amicus Separator, Mononuclear Cell Collection
Date Received: 15-DEC-00
Classification: III
Device Code: GKT

Dear Dr. Binion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act including requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

It should be noted that the products collected by this device are mononuclear cells and the Food and Drug Administration (FDA) is continuing to develop its regulatory approach for mononuclear cells. For further information, see FDA's "Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments," 63 Fed. Reg. 2985, January 20, 1998; the final rule, "Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing," 66 Fed. Reg. 5477, January 19, 2001; the proposed rule, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products," 64 Fed. Reg. 52696, September 30, 1999; and the proposed rule, "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement," 66 Fed. Reg. 1508, January 8, 2001.

If your device has been classified into either class II (Special Controls) or class III (Premarket Approval), (see above), it may be subject to the above and additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or it's labeling as being approved by FDA.

If you desire specific advice on promotional labeling and advertisement for your device, please contact our Advertising and Promotional Labeling Staff (HFM-602) at (301) 827-3028. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely,

Mark Weinstein, Ph.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research